PATENT COOPERATION TREATY

PCT

REC'D 28 FEB 2005

WIPO PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference RL-348WO	**FOR FURTHER ACTION**	See Form PCT/IPEA/416
International application No. PCT/IB2004/000821	International filing date *(day/month/year)* 19.03.2004	Priority date *(day/month/year)* 21.03.2003
International Patent Classification (IPC) or national classification and IPC A61K9/20		
Applicant RANBAXY LABORATORIES LIMITED et al		

1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 8 sheets, including this cover sheet.
3. This report is also accompanied by ANNEXES, comprising:
   a. ☐ *sent to the applicant and to the International Bureau)* a total of sheets, as follows:
      ☐ sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).
      ☐ sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.
   b. ☐ *(sent to the International Bureau only)* a total of (indicate type and number of electronic carrier(s)) , containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).

4. This report contains indications relating to the following items:

☒	Box No. I	Basis of the opinion
☐	Box No. II	Priority
☒	Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
☐	Box No. IV	Lack of unity of invention
☒	Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
☐	Box No. VI	Certain documents cited
☐	Box No. VII	Certain defects in the international application
☒	Box No. VIII	Certain observations on the international application

Date of submission of the demand	Date of completion of this report
20.01.2005	01.03.2005
Name and mailing address of the international preliminary examining authority: European Patent Office - P.B. 5818 Patentlaan 2 NL-2280 HV Rijswijk - Pays Bas Tel. +31 70 340 - 2040 Tx: 31 651 epo nl Fax: +31 70 340 - 3016	Authorized Officer von Eggelkraut-Gotta Telephone No. +31 70 340-4732

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/IB2004/000821

Box No. I Basis of the report

1. With regard to the **language**, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.

   ☐ This report is based on translations from the original language into the following language , which is the language of a translation furnished for the purposes of:
   - ☐ international search (under Rules 12.3 and 23.1(b))
   - ☐ publication of the international application (under Rule 12.4)
   - ☐ international preliminary examination (under Rules 55.2 and/or 55.3)

2. With regard to the **elements*** of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:

   Description, Pages

   1-9 as originally filed

   Claims, Numbers

   1-50 as originally filed

   ☐ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing

3. ☐ The amendments have resulted in the cancellation of:
   - ☐ the description, pages
   - ☐ the claims, Nos.
   - ☐ the drawings, sheets/figs
   - ☐ the sequence listing *(specify)*:
   - ☐ any table(s) related to sequence listing *(specify)*:

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).
   - ☐ the description, pages
   - ☐ the claims, Nos.
   - ☐ the drawings, sheets/figs
   - ☐ the sequence listing *(specify)*:
   - ☐ any table(s) related to sequence listing *(specify)*:

* *If item 4 applies, some or all of these sheets may be marked "superseded."*

Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application,

☒ claims Nos. 49 and 50 with respect to industrial applicability

because:

☒ the said international application, or the said claims Nos. 49 and 50 with respect to industrial applicability relate to the following subject matter which does not require an international preliminary examination (specify):

see separate sheet

☐ the description, claims or drawings *(indicate particular elements below)* or said claims Nos. are so unclear that no meaningful opinion could be formed *(specify)*:

☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.

☐ no international search report has been established for the said claims Nos.

☐ the nucleotide and/or amino acid sequence listing does not comply with the standard provided for in Annex C of the Administrative Instructions in that:

the written form	☐	has not been furnished
	☐	does not comply with the standard
the computer readable form	☐	has not been furnished
	☐	does not comply with the standard

☐ the tables related to the nucleotide and/or amino acid sequence listing, if in computer readable form only, do not comply with the technical requirements provided for in Annex C-*bis* of the Administrative Instructions.

☐ See separate sheet for further details

Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	7,11,12,14-28,35-37,42-48,50
	No:	Claims	1-6,8-10,13,29-34,38-41,49
Inventive step (IS)	Yes:	Claims	24, 27, 47
	No:	Claims	1-23, 25,26,28-46,48-50
Industrial applicability (IA)	Yes:	Claims	1-48
	No:	Claims	

2. Citations and explanations (Rule 70.7):

see separate sheet

Box No. VIII Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

see separate sheet

III. Re Item III

Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1.

1. Claims 49 and 50 relate to subject-matter considered by this Authority to be covered by the provisions of Rule 67.1(iv) PCT. Consequently, no opinion will be formulated with respect to the industrial applicability of the subject-matter of these claims (Article 34(4)(a)(i) PCT).

V. Re Item V

Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

For the assessment of the present claims 49 and 50 on the question whether they are industrially applicable, no unified criteria exist in the PCT Contracting States. The patentability can also be dependent upon the formulation of the claims. The EPO, for example, does not recognize as industrially applicable the subject-matter of claims to the use of a compound in medical treatment, but may allow, however, claims to a known compound for first use in medical treatment and the use of such a compound for the manufacture of a medicament for a new medical treatment.

2. Reference is made to the following documents:

D1 : US 6 031 004 A (BRETNALL ALISON E ET AL) 29 February 2000 (2000-02-29)

D2 : WO 01/39749 A (JAIN RAJESH ; SINGH AMARJIT (IN); PANACEA BIOTEC LTD (IN)) 7 June 2001 (2001-06-07)

D3 : EP 1 004 304 A (SUMITOMO PHARMA) 31 May 2000 (2000-05-31)

D4: ROTE LISTE SERVICE GMBH (ED): "Rote Liste 2002" 2002, ROTE LISTE 2002. ARZNEIMITTELVERZEICHNIS FUER DEUTSCHLAND (EINSCHLIESLICH EU - ZULASSUNGEN UND BESTIMMTER MEDIZINPRODUKTE), AULENDORF : EDITIO CANTOR, DE,GLUCOPHAGE (12054) , XP002287756 ISBN: 3-87193-252-3

3. INDEPENDENT CLAIMS 1, 29 and 49

1. The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claims 1, 29 and 49 is not new in the sense of Article 33(2) PCT.

2. Document D1 discloses (the references in parenthesis applying to this document): Tablets comprising metformin succinate, xylitol and flavours (examples 9 and 10). The disclosure of document D1 falls within the scope of protection sought for tablets comprising a salt of metformin, at least one sugar alcohol and at least one additional water-soluble excipient. The term water-soluble is broadly construed. No experimental conditions are given that would enable the skilled person to verify whether a tablet falls within the scope of the claims or not. The tablets disclosed in D1 are therefore considered to fall within the scope of claims 1,29 and 49, for they comprise the water-soluble excipients as claimed.

4. DEPENDENT CLAIMS 2-23, 25, 26, 28, 30-46, 48, 50

1. Dependent claims 2-23, 25, 26, 28, 30-46, 48, 50 do not contain any features which, in combination with the features of any claim to which they refer, meet the requirements of the PCT in respect of novelty and/or inventive step (Article 33(2) and (3) PCT).

2. Document D2 discloses (the references in parenthesis applying to this document): Fast dissolving tablets comprising cetirizine dihydrochloride, mannitol, polyvinylpyrrolidone, aspartame and sodium chloride (example 5). The description discloses that the invention is useful for the formulation of a range of different drugs and their salts, including metformin (page 3, paragraph 3 - page 4, last line).

3. Document D3 discloses (the references in parenthesis applying to this document): Tablets comprising metformin, ascorbic acid, mannitol, HPMC

(hydroxypropylmethylcellulose) (paragraph 71). The compositions may also comprise xylitol (claim 7).

4. Tablets comprising polyethylene glycol and metformin salt are known from documents D4, namely from the commercial product Glucophage ®.

5. DEPENDENT CLAIMS 24, 27, 47

1. The combination of the features of dependent claims 24, 27, 47 is neither known from, nor rendered obvious by, the available prior art. The reasons are as follows: Neither of documents D1 to D4 discloses or suggests water-soluble tablets comprising a salt of metformin and sodium propionate, nor are water-soluble tablets comprising a salt of metformin, micronized polyethylene glycol, xylitol and spray-dried mannitol disclosed.

VIII. Re Item VIII
Certain observations on the international application

6. The application does not meet the requirements of Article 6 PCT, because claims 1-5, 8, 18-23, 27, 29-33, 39, 44, 45, 47 and 49 are not clear.

1. Claims 1-5, 29-31 do not meet the requirements of Article 6 PCT in that the matter for which protection is sought is not clearly defined. The claims attempt to define the subject-matter in terms of the result to be achieved, which merely amounts to a statement of the underlying problem, without providing the technical features necessary for achieving this result. Said the technical teaching of said claims does not enable the skilled person to arrive at a tablet having the claimed properties without undue burden. Furthermore, the claims lack indication of the temperature under which the testing is to be performed.

2. The term "about" used in claims 1-5,8, 19-23, 29-33, 39, 45 and 49 is vague and unclear and leaves the reader in doubt as to the meaning of the technical features to which it refers, thereby rendering the definition of the subject-matter of said claims unclear, Article 6 PCT.

3. The term "micronized" used in claims 18, 27, 44 and 47 is vague and unclear and leaves the reader in doubt as to the meaning of the technical features to which it refers, thereby rendering the definition of the subject-matter of said claims unclear, Article 6 PCT.

4. Claim 47 refers to a "process according to claim 28", although claim 28 is a product claim. Claim 47 is therefore not clear.